IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	
	)	Group Art Unit:
Schulter, et al.	)	
	)	
Serial No.: New	)	Examiner:
	)	
Filed:	)	
	)	Attorney Docket No.: 023958.42192
For: BIOCOMPATIBLE FORM AND METHOD OF FABRICATION	)	

REQUEST TO CONSIDER INFORMATION DISCLOSURE STATEMENT FILED IN PARENT APPLICATION

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

The above-captioned, new utility patent application is a division of pending U.S. Patent Application Serial No. 10/012,652 filed October 30, 2001 and entitled "Biocompatible Form and Method of Manufacture" (the '652 Application).

During the prosecution of the '652 Application, Information Disclosure Statements were filed on May 11, 2002 and November 7, 2002. Copies of the foregoing Information Disclosure Statements are enclosed herewith as well as each of the documents listed on the corresponding Forms PTO-1449. The Examiner is respectfully requested to consider the foregoing Information Disclosure Statements (filed for the '652 Application) with regard to the examination of the

claims of the above-captioned, new utility patent application and is also requested to make each of the documents listed on the foregoing Information Disclosure Statements (filed for the '652 Application) of record in the above-captioned, new utility patent application.

Respectfully Submitted,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

8-7-03
Date

By: Susan B Fentress
SUSAN B. FENTRESS
Reg. No. 31,327

6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119
(901) 680-7319

U.S. Express Mail Label No. EU771896275US

MEMPHIS 80911v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of :	)	
	)	
Carl W. Schulter	)	Group Art Unit: 3738
	)	
Serial No.: 10/012,652	)	Examiner:
	)	
Filed: October 30, 2001	)	Attorney Docket No.: 023958.42192
	)	
	)	
For: BIOCOMPATIBLE FORM AND METHOD OF FABRICATION	)	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

As a means of complying with the duty of disclosure set forth in 37 C.F.R. §1.56, one sheet of Form PTO-1449 is being submitted herewith, together with full text copies of each of the documents listed thereon.

Document AB discloses a Combination Tray and Condylar Prosthesis for Mandibular Reconstruction and the Like. The invention comprises a urethane-coated polyethylene terephthalate mesh bone induction tray, with a simulated condyle integrally affixed to the mesh tray without the use of metal pins, screws and the like (Abstract). The invention lies in the integral affixing of a urethane plastic, e. g., polyether urethane simulated condyle to the end portion of a plastic tray (Abstract). The simulated condyle may be customized, i. e., premeasured for a particular patient before the operation, or may be custom-contoured from one of several pre-formed condyle/tray combinations having varying shapes or geometries (Abstract).

Document AF discloses a Method and Apparatus for Growing Jaw Bone Utilizing a Guided-Tissue Regeneration Plate Support and Fixation System. In the Background of the Invention portion of the patent, Robinson indicates that bone grafting has become an essential element for the successful treatment for those who do not have enough bone for dental implants (Col. 1, lines 27-29). Robinson further indicates that, as viable methods, blocks of hip bone have been affixed to the jaw and freeze-dried, demineralized bone protein has been used as a stimulant to cause the patient's bone cells to become active and lay down new bone onto the existing bone areas and into the new bone graft areas (Col. 1, lines 27-34). Further, Robinson states that

through experience and research, it has become evident that for bone grafting to be successful, it must be given an isolated space to grow, protected from muscular pressure, tissue impingement and chewing forces (Col. 1, lines 34-37).

Robinson discloses a method of growing jaw bone and the related guided-tissue regeneration plate support and fixation system employed in the method where an isolated and protected space free from tissue impingement, occlusal loading, chewing forces or muscular pressure is created between the periosteum and the jaw bone (Abstract). This space is created by first placing either a dental implant or a guided-tissue regeneration plate support and fixation system tenting-type support screw into the jaw bone (Abstract). The plate portion of the guided-tissue regeneration plate support and fixation system is preferably made out of Grade 1 commercially pure titanium, which is the fully annealed form of titanium advantageously characterized in that it will not spring back after being bent (Abstract; Col. 4, lines 18-26). The guided-tissue regeneration plate support and fixation system is adapted to be surgically removed after the bone has grown under its surface at a later uncovering or implant placement surgery (Col. 2, lines 55-58).

Fig. 1 illustrates an exemplary existing midline cross-section of a maxillary edentulous ridge which has undergone substantial bone loss, with Fig. 1 illustrating a palatal bone 1, a floor of the nose 2, a bony ridge 3, and a gum tissue 4 (Fig. 1; Col. 5, lines 9-13). Fig. 4 depicts the mating of the guided-tissue regeneration plate 12 to a guided-tissue regeneration support screw 11 which is placed into the bony ridge 3 (Col. 5, lines 29-36). Fig. 5 illustrates the bone graft material 14 packed beneath the plate 12 and Fig. 6 illustrates how the bony ridge appears after the guided-tissue regeneration plate support and fixation system has been removed to expose the new bony ridge 15 (Figs. 4 and 5; Col. 5, lines 40-49).

Document AG discloses an Osseo-Integrated Sub-Periosteal Implant. Robinson discloses a sub-periosteally implantable prosthesis support structure for a fixed or detachable dental prosthesis which includes a framework fitted to and generally conforming to the inner and outer contours of the maxillary and/or mandibular bony ridge structures of a person (Abstract; column 2, lines 47-52). The framework is configured in cross section to provide a space extending generally normal to the bony ridge structure to an apex to provide space beneath the apex for subsequent bone growth (column 2, lines 52-56). A plurality of dental prosthesis support posts are distributed about and affixed to the framework and depend outwardly from the apex in substantial alignment with the bony ridge structure of the person when the support structure has been sub-periosteally implanted (column 2, lines 56-60). During the fabrication of the prosthesis support structure,

a bio-compatible fine mesh screen is fixed to and spans, tent-like, the framework to substantially overlay the implant structure and the space provided for subsequent bone growth (column 2, lines 60-64). After the support structure has been sub-periosteally implanted, the growth of bone into the space and around the support structure is promoted to osseo-integrate the support structure with the person's bony ridge, thus providing a secure foundation for a dental prosthesis configured for coupling with the sub-periosteal dental implant support posts (column 2, line 64 to column 3, line 3).

Figs. 1-3 illustrate a first embodiment of the disclosed invention which is suited for use in the maxillary position and which includes a framework 1, which may be fabricated from titanium stock and is preferably fabricated as a one-piece casting (column 3, lines 20-28; column 5, lines 4-8). The framework 1 provides a series of support posts 2 for receiving a detachable denture and to promote growth of the maxillary bony ridge of a patient to which the prosthesis support structure has been fitted (column 4, lines 1-7). The framework 1 is shown covered with a mesh screen 5 which may be fabricated from any bio-compatible material, such as titanium, suitable as to strength and appropriate for permanent retention in the mouth of an individual (column 4, lines 17-24). Robinson further indicates that, in some applications, the screen 5 may alternatively be fabricated from a resorbable material such as Vicryl™ (column 4, lines 24-26). Robinson indicates that the mesh 5 may be attached to the framework 1 by any suitable means such as with an adhesive or by welding, spot welding being particularly suitable when the then-preferred material, titanium, is used, or by sintering or even by the use of suitably placed ligatures (column 4, lines 60-65).

Figs. 4-6 illustrate a prosthesis support 14, which is suitable for use in the mandibular position and includes a mandibular framework 10 and screen 15 (column 3, lines 29-38; column 5, lines 9-14).

Robinson indicates that the regular and symmetrical prosthesis supports 4, 14 shown in Figs. 1-6 are idealized and that those prosthesis supports prepared for an individual patient may, in fact, be considerably irregular and asymmetrical (column 5, lines 33-37). Robinson further states that the complete prosthesis supports 4, 14 are individually fabricated by a dental technician over a casting made from impressions of a given patient's maxillary and/or mandibular gum/bony ridge regions and that accordingly, each prosthesis support 4 and/or 14 will be a close, tent-like fit over the maxillary and/or mandibular bone structures and under the gum tissue of the given patient at the time of fitting (column 5, lines 37-45).

Document AQ is a brochure, date unknown, published by Pacific Coast Software, Inc. which discusses

a software product directed to dental implant treatment planning identified as ImPlacer.™

The remaining documents provide technical background for the general field of the invention. It is respectfully requested that the documents disclosed herein be made of record and considered in connection with the examination of the claims of the captioned patent application.

In the event an extension of time is required to consider this document, the Commissioner is respectfully requested to consider this a petition therefor. Also, if additional fees are required to consider this document, the Commissioner is hereby expressly authorized to charge any such fees to Deposit Account No. 50-0858.

In the event the Examiner has any questions regarding this document, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

BUTLER, SNOW, O'MARA
STEVENS & CANNADA, PLLC

Date: May 11, 2002

By: Bradley D. Beck

Post Office Box 171443
Memphis, TN 38187
Telephone: 901-680-7311

Bradley D. Beck
Registration No. 35,440

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, on May 11, 2002 in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Bradley D. Beck
BRADLEY D. BECK

#36899v1<Memphis> -Schulter Information Disclosure Statement 03-14-02.wpd

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
023958.4219	10/012,652
Applicant(s)	
Carl W. Schulter	
Filing Date	**Group Art Unit**
October 30, 2001	3738

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,522,596	06/11/85	Ashkinazy	433	173	
	AB	4,636,215	01/13/87	Schwartz	623	16	
	AC	5,380,328	01/10/95	Morgan	606	70	
	AD	5,658,516	08/19/97	Eppley et al.	264	251	
	AE	5,769,637	06/23/98	Morgan	433	176	
	AF	5,839,899	11/24/98	Robinson	433	215	
	AG	6,030,218	02/29/2000	Robinson	433	173	
	AH	6,152,737	11/28/2000	Beaty et al.	433	172	
	AI	6,217,333	04/17/2001	Ercoli	433	173	
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AQ	
	AR	Pacific Coast Software Inc., Brochure entitled, "See it. Plan it. Store it," Date Unknown, Front and Back Cover Pages and four (4) pages of inserts.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	
	)	Group Art Unit No.: 3738
CARL W. SCHULTER	)	
	)	
Serial No.: 10/012,652	)	Examiner:
	)	
Filed: October 30, 2001	)	
	)	Attorney Docket No.: 023958.42192
For: BIOCOMPATIBLE FORM AND METHOD OF FABRICATION	)	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D. C. 20231

Sir:

As a means of complying with the duty of disclosure set forth in 37 C.F.R. §1.56, one sheet of Form PTO-1449 is being submitted herewith, together with full text copies of each of the documents listed thereon.

Document FR 2 713 090 discloses a device consisting of a metallic membrane (3) of rigid construction, shaped to conform to the tissue portion (2) to be regenerated. The membrane may typically be formed as a tunnel-shaped shell (4), with an internal concave space (5) allowing tissue growth. The membrane may be formed of e.g. titanium, with an internal concave surface (6) which is polished or smooth and an external convex surface (7) which is roughened. The edge portions of the membrane fit into longitudinal grooves formed in edge joints (10) which define a stabilizing seal against the lower portions of the tissue to be regenerated.

It is respectfully requested that the documents disclosed herein be made of record and considered in connection with the examination of the claims of the captioned patent application.

In the event an extension of time is required to consider this document, the Commissioner is respectfully requested to consider this a petition therefore. Also, if additional fees are required to consider this document, the Commissioner is hereby expressly authorized to charge any such fees to Deposit Account No. 50-0858.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
023958.42192	10/012,652
Applicant(s)	
Schulter, Carl W.	
Filing Date	**Group Art Unit**
October 30, 2001	3738

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,030,218	02/29/00	Robinson	433/173		04/12/99
		5,769,637	06/23/98	Morgan	433/176		05/22/96

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
		EP 1 106 145 A2	06/13/01	Europe	8/00			✓
		FR2 713 090 A1	09/06/95	France	27/00			✓

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CERTIFICATE OF MAILING

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_____

LORI L. WOOD

MEMPHIS 65037v1

In the event the Examiner has any questions regarding this document, please contact the undersigned at the telephone number listed below.

Respectfully Submitted,
BUTLER, SNOW, O'MARA, STEVENS
& CANNADA, PLLC

11-7-02
Date

By: Stephen Michael Patton
STEPHEN MICHAEL PATTON
Reg. No. 36,235
Post Office Box 171443
Memphis, TN 38187
Telephone: 901-680-7311
Fax: 901-680-7201

CERTIFICATE OF MAILING

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LORI L. WOOD

MEMPHIS 65093v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	
	)	Group Art Unit No.: 3738
CARL W. SCHULTER	)	
	)	
Serial No.: 10/012,652	)	Examiner:
	)	
Filed: October 30, 2001	)	
	)	Attorney Docket No.: 023958.42192
For: BIOCOMPATIBLE FORM AND METHOD OF FABRICATION	)	

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D. C. 20231

Sir:

The Information Disclosure Citation for the above-captioned application is enclosed herewith.

Respectfully Submitted,
BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

11-7-02
Date

By: Stephen Michael Patton

STEPHEN MICHAEL PATTON
Reg. No. 36,235
Post Office Box 171443
Memphis, TN 38187
Telephone: 901-680-7311
Fax: 901-680-7201